



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration

466 Fernandez Juncos Avenue  
Puerta De Tierra  
San Juan, Puerto Rico 00901-3223

April 17, 2001

**WARNING LETTER**  
**SJN-01-08**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Hector Fabre  
Borinquen Biscuit Co.  
State Road 376 Km. 0.1  
Barriada LLuveras  
Yauco, PR 00698

CFN: 1000536528  
Product: Wheat Flour 86/44kgs Bag  
Reference Number: 261-0409203-1  
Customs Sample/Entry No: 261-0409203-1

Dear Mr. Fabre:

The Food and Drug Administration (FDA) attempted to examine a shipment of wheat flour products offered for importation into the United States by your firm on or about March 21, 2001, under entry number 261-0409203-1, and found that the shipment was not held intact pending receipt of "May Proceed" and or availability for FDA examination. Our inspector visited your firm on March 30, 2001, based on information supplied to us by your broker that the product was ready for inspection. Upon arrival at your facility, our inspector was advised that 86 bags of the 100 bags received had already been distributed without an FDA release.

This is a violation of Section 801 (a) of the Federal Food, Drug and Cosmetic Act (the ACT) and Title 21, Code of Federal Regulations (CFR), Part 1.90, which requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the product was not made available to us for examination we have requested the U.S. Customs Service (Customs) to order redelivery of the Wheat Flour which have been distributed without a release from FDA (copy of the request is enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and the regulations promulgated thereunder.

04/16/01

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mildred R. Barber".

Mildred R. Barber  
San Juan District Director